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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,492	07/21/2003	Karen Jackson	330499.00009	4987
27160	7590	04/03/2006	EXAMINER	
KATTEN MUCHIN ROSENMAN LLP			COOK, REBECCA	
525 WEST MONROE STREET			ART UNIT	
CHICAGO, IL 60661-3693			PAPER NUMBER	

1614

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/622,492	Applicant(s) JACKSON, KAREN	
	Examiner Rebecca Cook	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-45 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/5/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112, Second Paragraph

Claims 1-2 and 4-45 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In amended claim 1 the intent of the word "superpotentiating" is not clear and it is still not seen how it differs over "potentiating." Stedman's Medical Dictionary discloses that "potentiate" means "increase the effect of or act synergistically with." A search of the Web and Webster's II dictionary did not yield a definition for the word "superpotentiate" or "superpotentiating" other than what appears to be applicant's own work.

Applicant argues that "superpotentiating" means that the method yields a particular type of synergy that requires both reducing the opioid dosage while increasing the pain relief experienced by the patient. This is not persuasive since it is not claimed. The claim recites that "a therapeutically effective amount of an analgesic" is required, not that the opioid dosage is reduced or that pain relief is increased. Furthermore, the claims are not limited to only an opioid analgesic. A search of the Web and Webster's II dictionary did not yield a definition for the word "superpotentiate" or "superpotentiating" other than what appears to be applicant's own work.

Additionally, the data in the specification do not support both reducing the opioid dosage while increasing the pain relief experienced by the patient. Paragraph 43 on page 15 discloses only that "several patients markedly reduced their daily opioid

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dosage." Nothing is disclosed regarding increased pain relief. Furthermore, the data only supports opioids, not all analgesics.

In view of the amendments to the claims the earlier rejections are overcome.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 and 4-45 are again rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/18967 (Panos et al). Applicant argues that Panos et al do not show or could not be used to predict that devazepide itself can act or enable the overall dose of opioid to be reduced or minimized, concurrent with improved analgesia. This is not persuasive. The data in the specification is persuasive only for "potentiating," and not for the level of pain going down accompanied by the dose of opioid going down.

Claims 1-2 and 4-45 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Dourish et al.

Applicant argues that Dourish et al is counter-intuitive to devazepide acting as a superpotentiater, enabling the overall dose of opioid to be reduced or minimized, concurrent with improved analgesia. This is not persuasive. The data in the specification is persuasive only for "potentiating," and not for the level of pain going down accompanied by the dose of opioid going down.

Terminal Disclaimer

The terminal disclaimer filed on November 15, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,713,470 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Action Is Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 571-273-8300.

Rebecca Cook

A handwritten signature in cursive script that reads "Rebecca Cook".

Primary Examiner
Art Unit 1614

March 29, 2006